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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

CHURCH & DWIGHT CO., INC., a Delaware corporation, Plaintiff, v. SPD SWISS PRECISION DIAGNOSTICS GmbH, a Swiss Corporation, Defendant.	Case No. 14-CV-585 (AJN) **SPD SWISS PRECISION DIAGNOSTICS, GMBH'S REPLY MEMORANDUM IN SUPPORT OF ITS MOTION TO DISMISS** Hon. Alison J. Nathan Trial Date: None Set

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INTRODUCTION

This lawsuit is an attempt by Church & Dwight Co., Inc. ("C&D") to overturn the U.S. Food and Drug Administration's ("FDA") exercise of its regulatory authority under Section 513(i)(1)(E) of the Food, Drug and Cosmetic Act ("FDCA"). The FDA cleared the Clearblue Advanced Pregnancy Test with Weeks Estimator ("Weeks Estimator" or "Product") for sale in the U.S., allowing SPD Swiss Precision Diagnostic, GmbH ("SPD") to market the Weeks Estimator's unique ability to estimate weeks since a pregnant woman's ovulation. This clearance, granted pursuant to this rarely-invoked section of the FDCA, allowed the FDA to require certain very specific disclosures that it considered adequate to avoid consumer confusion between weeks since ovulation and the still-common medical convention of dating pregnancy from a woman's last menstrual period ("LMP"). Now C&D seeks to stop SPD from marketing the Weeks Estimator altogether, and to impose damages on SPD based on the supposed inadequacy of the very disclosures in the "Indications for Use" (IFU) and the Package Insert that the FDA itself wrote, determined to be adequate to eliminate any risk of confusion or improper use by consumers, and required SPD to make.[1]

Such a claim, whether under the Lanham Act or under state law, should be dismissed by this Court as barred under long-standing precedent that is not affected by the Supreme Court's pending consideration of the much different facts of the *Pom Wonderful* case. Dismissal is further supported by the clear evidence that C&D itself approached the FDA with its concerns about the Weeks Estimator, in effect submitting two letter briefs to the FDA and asking for the FDA to exercise its authority over the Weeks Estimator advertising based on the allegations

[1] While the pertinent documents debunk C&D's contention that SPD has ***not*** complied with FDA requirements, dismissal would be required even if that contention were true. Only the FDA can enforce its decision under the FDCA. Indeed, the fact that the FDA evaluated C&D's contentions and declined to take the action C&D seeks (i.e., to stop the marketing of the Weeks Estimator) underscores why the doctrine of FDA preclusion exists.

C&D asserts now in its complaint. In fact, the FDA did act and did review SPD's marketing materials again. At no point did the FDA make any finding that SPD's materials were false or misleading; rather, it has allowed the Weeks Estimator to continue to be marketed with the same essential message – i.e., that the Product can estimate weeks since ovulation, and that this estimate is different from a doctor's estimate of the duration of pregnancy based on LMP. The FDA's second review confirms its conclusion that the specific language it required in the IFU and in the Package Insert were sufficient to avoid any confusion or risk from customers using the device as if it provided the same information as a doctor's estimate.

Finally, the Court should reject C&D's effort to delay dismissal of this action in order to conduct discovery. C&D filed this lawsuit knowing full well that it had sought relief from the FDA, but without disclosing that fact (choosing instead to provide a partial record of FDA proceedings by attaching only the 2012 clearance letter to its Complaint). The FDA's exercise of its statutory authority over SPD's advertising materials is undisputed. Similarly, there can be no dispute that the FDA approved slight modifications to SPD's packaging and a mitigation plan for the other challenged advertising. Discovery of SPD's internal communications will shed no light on what the FDA did. Through judicial notice or, if necessary, by converting this motion to one for summary judgment, the Court can and should act on this record now to dismiss the case.

ARGUMENT

I. C&D's Claims Are Precluded By FDA Action.

A. C&D's Request For Relief To The FDA Confirms That Preclusion Is Appropriate.

Documents C&D produced under this Court's March 21 order show that C&D itself has acknowledged the FDA's authority over the issues C&D raises here. On October 10, 2013, C&D wrote to the FDA asking it to take "corrective action" against SPD for having purportedly "violate[d] the labeling restrictions imposed in the Clearance Letter." (SPD's Supplemental

Request For Judicial Notice ["Supp. RJN"], submitted concurrently herewith, Ex. A.) In that letter brief and a second one on November 1, 2013, C&D attacked the same advertising it attacks here, on the same theory. (*See* Supp. RJN, Ex. A at CD0000002, CD0000004, Ex. B at CD0000037 & CD0000038.)

The FDA ***did*** investigate C&D's allegations, notifying SPD in November 2013 of its intention to evaluate SPD's advertising, thus beginning the discussions detailed in SPD's opposition to the preliminary injunction motion. (SPD's Memorandum of Law in Opposition to Motion for Preliminary Injunction at 9-12.)[2] And although the FDA had authority to order SPD to stop marketing the product, to impose monetary penalties or simply to find officially that the challenged advertising was misleading, it did none of those things.[3] (SPD's March 4, 2014 Request For Judicial Notice ["RJN"], Ex. I.)

C&D's choice to petition the FDA reinforces the conclusion that its claim is precluded. In *PhotoMedex, Inc. v. Irwin*, 601 F.3d 919 (9th Cir. 2010), PhotoMedex sued under the Lanham Act after attempting to persuade FDA to "take immediate enforcement action" against a competing medical device manufacturer for purported violations of the FDA clearance process. The Ninth Circuit ruled PhotoMedex's Lanham Act claim was precluded, stating: "That PhotoMedex engaged in an extensive campaign to try to convince the FDA to act on Ra

[2] In the course of that inquiry, the FDA has effectively rejected C&D's claims about the Weeks Estimator packaging. Despite C&D's advocacy, the FDA expressly approved labeling elements that C&D contends convey a false message (*e.g.*, SPD's use of the phrase "weeks along"). And, even though the FDA has reviewed and approved every detail of SPD's *current* packaging, C&D nonetheless asserted at the April 4, 2014 case management conference that C&D intends to challenge this packaging on the same basis as it is challenging the earlier version. Such a challenge, which does not appear in C&D's complaint, is also precluded by the FDA's action, [redacted] SPD will address these points separately.

[3] C&D asserts that the FDA did not engage "in any pre-clearance review whatsoever of the Commercial or the other non-label advertising the Complaint alleges to be false." (C&D's Memorandum of Law in Opposition to Defendant's Motion to Dismiss ("Opp.") at 20.) This phrasing allows C&D to ignore the fact that, at C&D's request, the FDA ***did*** investigate non-label advertising ***including*** the Commercial, after the Weeks Estimator was launched in 2013. (RJN, Ex. I at 7.) Thus, the FDA ***has*** reviewed the non-label advertising C&D challenges and has elected to take certain steps and not others. To allow C&D to maintain this action would be to allow C&D to use this lawsuit to second-guess and disrupt the very FDA review and decision-making that ***C&D itself*** requested.

Medical's supposed misstatements and violations demonstrates that PhotoMedex understood that this subject fell within the FDA's domain." *Id.* at 930. The same is true here.

C&D attempts to distinguish *PhotoMedex* by asserting that "C&D does not allege that SPD's advertising was false because SPD did not obtain clearance for the intended use of telling a woman how many weeks she has been pregnant." (Opp. at 17.) But C&D not only made this allegation, it is a central theme of C&D's complaint. In the ***third paragraph***, C&D alleges "[t]he FDA cleared the Product to be marketed for the former use [estimating weeks since ovulation], ***but expressly prohibited SPD from marketing the Product as a means for estimating the length of pregnancy***," and in the following paragraph alleges that SPD's marketing violates this prohibition. (Compl. ¶¶ 3-4 (emphasis added); *see also* Compl. ¶ 5) In addition, contrary to C&D's argument (Opp. at 16-17), *PhotoMedex* was not decided simply on the question whether a new clearance was necessary for the device at issue. The court there said: "To permit PhotoMedex to proceed with a claim that Defendants violated this law ***when the FDA did not so determine*** would, in effect, permit PhotoMedex to assume enforcement power which the statute does not allow and ***require the finder of fact to make a decision that the FDA itself did not make***." *PhotoMedex*, 601 F.3d at 930 (emphasis added).

A. <u>The *Lexmark* Decision on Standing Is Irrelevant.</u>

C&D's heavy reliance on *Lexmark Int'l, Inc. v. Static Control Components, Inc.*, 134 S. Ct. 1377 (2014), is misplaced. *Lexmark* had nothing to do with the interplay between the Lanham Act and the FDCA – the essence of the FDA preclusion question. Rather, it was a case about standing to sue under the Lanham Act – an issue not raised here. While addressing that issue, the Court observed that it was being asked to refrain from exercising jurisdiction based on purported "prudential" (*i.e.*, neither constitutional nor statutory) considerations – and that this request was "in some tension" with the general principle that "a federal court's 'obligation' to hear

and decide cases within its jurisdiction is 'virtually unflagging." *Id.* 1386.

The principle of FDA preclusion, however, is a ***statutory*** concept, not a prudential one. It seeks to reconcile the overlapping functions of the Lanham Act and FDCA so that a private litigant cannot use the former to undermine the provisions of the latter. It does not mean that the Court should "decline" to exercise jurisdiction; it means the Court should exercise its jurisdiction to conclude that the Lanham Act claim is ***barred*** because, if allowed to proceed, it would undermine the FDA's exercise of its exclusive authority under another federal statute.

B. C&D's *Pom Wonderful* Argument Is Legally Baseless and the Government's Brief Supports SPD's Position In This Case.

According to C&D, SPD has "utterly ignore[d] the significance" of the U.S. Supreme Court's grant of certiorari in *Pom Wonderful LLC v. Coca-Cola Co.*, 679 F.3d 1170 (9th Cir. 2012), *cert. granted*, 134 S. Ct. 895 (2014). Not so. The grant of certiorari itself does not "cast[] serious doubt on the viability of the Ninth Circuit's decision," or imply that reversal of *Pom Wonderful* is "looming," as C&D asserts. (Opp. at 13, 16.) Until the Court rules, the decision stands as applicable precedent. *See, e.g.*, *Bryson v. Gonzales*, 534 F.3d 1282, 1285 n.1 (10th Cir. 2008); *Ritter v. Smith*, 811 F.2d 1398, 1404-05 (11th Cir. 1987); *U.S. ex rel. Daneff v. Henderson*, 501 F.2d 1180, 1181 (2d Cir. 1974).

C&D's suggestion that the Government's briefs in *Pom Wonderful* support C&D's position is also wrong. The opposite is true, as reflected in the following passage:

> Success on petitioner's claim that the common name of respondent's juice was misleading would undo what the parties seemingly accept as FDA's regulations' specific pronouncement on that very subject. Accordingly, invocation of the general remedy under Section 43(a) of the Lanham Act specifically for the claim regarding the common name of respondent's juice is not 'capable of coexistence' with those regulations. ***Indeed the clash is particularly acute here because the content of FDA's naming regulations derives largely from the agency's answer to the question of what will and will not mislead juice consumers—essentially the question posed by petitioner's Lanham Act claim.***

(Declaration of Victoria L. Loughery, Ex. B at 18 (emphasis added) (citation omitted).)

This passage highlights the strength of the facts here in support of FDA preclusion. In *Pom Wonderful*, the preclusive FDA action consisted of a regulation of ***general*** application that permitted Pom Wonderful to make its labeling claim. *Pom Wonderful*, 679 F.3d at 1178. Here, the FDA invoked its statutory authority under Section 513(i)(1)(E) of the FDCA[4] specifically to review ***the entirety of the Weeks Estimator's label in light of the*** same concerns C&D voices in this action. (Compl. ¶¶ 24, 42-43, 50-53; Opp. at 11.) The FDA found that any potential confusion from misinterpretation of test results "may be prevented given adequate device labeling." RJN, ¶ 2, Ex. B ("Hold Letter"). The FDA ultimately ordered that SPD's packaging and advertising materials must include specific statements, particularly the IFU, that the FDA concluded were sufficient to avoid the identified risks.[5] (Compl. Ex. A ("Clearance Letter").) The FDA specifically approved SPD's sample package label and Package Insert. (RJN, Ex. G; Clearance Letter at 1-2.)[6] In November and December 2013 – after it received C&D's letter briefs – the FDA effectively rejected C&D's allegations that the Weeks Estimator package conveys a "false" or misleading message to consumers. (Supp. RJN, Ex. D; RJN, Ex. I.) Thus, the regulatory process reflects the FDA's repeated, specific and careful analysis of exactly the

[4] Section 513(i)(1)(E) of the FDCA is codified at 21 U.S.C. § 360c(i)(1)(E). The FDA's guidance document on this subject is attached to the RJN, Exhibit C.

[5] C&D continually mischaracterizes a single excerpt from the IFU. Referring to the phrase "[t]his test cannot be used to determine the duration of pregnancy," C&D insists that this means any message correlating ovulation with the start of pregnancy is false. (*See, e.g.*, Opp. at 20.) (Indeed, C&D repeatedly refers to this statement as an "admission" that SPD has sought to obscure with "tiny type," even though FDA specified the content, type size and location of the entire IFU.) Taken in context, this passage is plainly part of the FDA's effort to avoid confusion between estimating from ovulation and dating from LMP. FDA was very careful in its language, and the Weeks Estimator does not "determine" pregnancy "duration" but ***estimates*** weeks since ovulation, and therefore when pregnancy begins. (Compl., Ex. A.)

[6] Predictably, C&D argues that, because there were two extremely minor differences between the Weeks Estimator label expressly approved by the FDA in the clearance process and the launch version of the label, the FDA's detailed review and approval should be disregarded. (Opp. at 9-10.) But, thanks to the inquiry instigated by C&D, we no longer have to guess whether these differences mattered to the FDA. FDA expressly approved a modified label in which the elements C&D complains about remain present. (*See* SPD's Motion To Dismiss at 7-8.) Indeed, C&D's stated intention to challenge the new packaging on the same ground as the old packaging is an admission that the packages are not materially different and that C&D is using this action to overturn the FDA's approval of SPD's current packaging.

issues now raised by C&D, and the FDA's determination that the labeling limitations sufficiently address any potential problem.

The Court should also reject C&D's assertion that, even if the FDA did approve the Weeks Estimator packaging as ***not*** misleading to consumers, C&D can still challenge the packaging as false because the statements required by the FDA appeared not only on the outside of the box, but also in the package insert. (Opp. at 4-5, 10.) Simply put, this dual disclosure outside and inside the box ***is what the FDA itself required and found to be sufficient to address any potential confusion by consumers.*** Any attempt to impose private liability on SPD for obeying the FDA's carefully considered directions as to what should be disclosed *and where* would be incompatible with the decision the FDCA empowers the FDA alone to make and to enforce.[7]

C. C&D's Effort To Rewrite The Case Law Fails.

According to C&D, the large body of FDA preclusion case law may be divided into three categories: Lanham Act claims that (1) were based solely on a purported FDCA violation; (2) would require interpretation of ambiguous FDA regulations; or (3) would require the court to countermand FDA's clearance of a product as safe and effective. (Opp. at 16.) C&D insists that its allegations fall into none of these categories.

At the threshold, C&D's classification is wrong. Indeed, *Pom Wonderful* fits into none of these categories. The plaintiff's claim there was entirely independent of any purported FDCA violation; the regulations at issue were not ambiguous; and there was no FDA clearance involved. Similarly, SPD cited a number of cases which, like this one, barred a challenge to

[7] C&D argues broadly that because the FDCA and Lanham Act have "distinct purposes," and because the latter allows a private claim for damages by a competitor and the former does not, the claims here cannot be precluded. But such contentions prove too much. If they were accepted, ***the entire line of authority applying the principle of FDA preclusion would be overturned.*** Even if the statutes are different, the courts have repeatedly recognized that a private party may not use the Lanham Act to override or circumvent the FDA's legitimate exercise of its exclusive authority under the FDCA precisely ***because*** the FDCA allows for no private right of action.

advertising because it complied with specific FDA approvals. *See*, *e.g.*, *Cytyc Corp. v. Neuromedical Systems, Inc*., 12 F. Supp. 2d 296, 301 (S.D.N.Y. 1998) (Lanham Act claim dismissed under Rule 12(b)(6) because advertising representations "that comport substantively with statements approved as accurate by the FDA cannot supply the basis" for such a claim); *SmithKline Beecham v. Johnson & Johnson-Merck*, No. 95-7011, 1996 U.S. Dist. LEXIS 7257 (S.D.N.Y May 24, 1996) (preliminary injunction denied because challenged advertising was based on labeling approved by the FDA); *Am. Home Products Corp. v. Johnson & Johnson*, 672 F. Supp. 135, 145 (S.D.N.Y. 1987) (FDA approval of label barred claim as a matter of law).

C&D has cited no case allowing a Lanham Act claim to overturn or revise the considered judgment of the FDA. For example, neither *Merck Eprova AG v. Gnosis S.P.A.*, No. 07-5898, 2011 U.S. Dist. LEXIS 30683 (S.D.N.Y. Mar. 17, 2011), nor *Merck Eprova AG v. ProThera, Inc.*, No. 08-35, 2010 U.S. Dist. LEXIS 142372, (S.D.N.Y. Oct. 20, 2010), appeared to involve ***any*** FDA approval, or even consideration, of the advertising claims being challenged. Those cases undermine C&D's effort to avoid preclusion based on its (false) contention that its claims have little or nothing to do with any FDCA- or FDA-imposed constraint. In both cases, the court observed that there was ***no*** allegation of a FDA violation (contrast that with C&D's complaint, which is littered with such allegations). There simply is no basis for C&D to avoid preclusion.

D. C&D's Contention That This Motion Presents Factual Questions Is Baseless.

In the parties' case management submission of April 22, 2014, C&D argued that the Court must make "factual determinations" in order to decide "whether FDA has already dealt with the complaints raised in the C&D's Complaint . . . ." (C&D's April 22, 2014 Letter at 2.) C&D insists that discovery on this issue is therefore necessary before the Court can decide it.

C&D is wrong. No discovery, and no factual determinations, are necessary to determine whether the FDA's actions preclude C&D's claim. There can be no dispute about the FDA's

legal authority, or how it exercised that authority here. The FDA cleared the Weeks Estimator in 2012, subject to very specific labeling and disclosure requirements (Clearance Letter), and then in 2013, at C&D's request, it reviewed SPD's advertising materials again. In that second review, the FDA approved SPD's packaging and mitigation plan and did ***not*** require the "corrective action" C&D now seeks from this Court. The FDA also indicated to C&D that it considers this entire matter to be a continuing investigation within its authority under Section 513(i)(1)(E). (*See* Supp. RJN, Ex. D.) No discovery is necessary for this Court to consider these undisputed facts. Dismissal should be granted now.

II. C&D'S Claims Should Be Dismissed Based On Primary Jurisdiction.

C&D's argument that the doctrine of primary jurisdiction is inapplicable here is particularly hypocritical. Just a few years ago, it argued successfully that: "[i]t is the responsibility of the FDA, not a state or federal court, to determine the appropriate scope and content of warning labels for a particular medical device." *Gordon v. Church & Dwight Co.*, No. 09-5585, 2010 WL 1220666, at 8 (N.D. Cal. Feb. 3, 2010) (citations omitted).

C&D advances two fallacies to justify its about-face: first, that primary jurisdiction is appropriate only when the FDA has promulgated a comprehensive set of regulations governing labeling of a category of device (essentially, that the FDA's regulations must "occupy the field," a *preemption* concept), and second, that SPD's advertising violates the FDA's limitations on the Weeks Estimator product. These fallacies are readily refuted.

A. C&D Ignores The Second Circuit's Four Factor Analysis.

C&D cites to no case suggesting that primary jurisdiction can be invoked only when the FDA has promulgated comprehensive category-specific regulations. As reflected in the case law cited by both parties, the Second Circuit focuses instead on four factors when assessing the applicability of the doctrine: (1) whether the question at issue is within the conventional experience of judges, or whether it involves considerations within the agency's particular field of

expertise; (2) whether the question at issue is particularly within the agency's discretion; (3) whether there exists a substantial danger of inconsistent rulings; and (4) whether a prior application to the agency has been made. *Ellis v. Tribune Television Co.*, 443 F.3d 71, 82-83 (2d Cir. 2006); *Bernhardt v. Pfizer, Inc.*, No. 00-4042, 2000 US Dist. LEXIS 16963, at *5 (S.D.N.Y. Nov. 16, 2000); *In re Methyl Tertiary Butel Ether Products Liab. Litig.*, No. 00-1898, 2007 US Dist. LEXIS 18398, at *6 (S.D.N.Y. Mar. 6, 2007); *Jovel v. I-Health, Inc.*, No. 12-5614, 2013 US Dist. LEXIS 139661 at *19-20 (E.D.N.Y. Sept. 27, 2013).

All four factors weigh heavily in favor of deferring to the FDA: (1) whether the disclosures the FDA mandated are sufficient to prevent consumer confusion about how a doctor dates pregnancy, as compared to how the Weeks Estimator estimates weeks since ovulation, is within the FDA's specialized medical and scientific expertise; (2) whether SPD's marketing violates or complies with the FDA's directives under Section 513(i)(1)(E) of the FDCA is uniquely within the FDA's purview; (3) a court decision granting C&D's requested relief would contradict decisions the FDA has already made and could interfere with its ongoing regulatory process; and (4) C&D has complained to the FDA about precisely these issues, and the FDA has acted on C&D's complaints.

As for C&D's second argument, it cherry-picks ***one statement*** from the IFU – that the test should not be used to "determine the duration of pregnancy" – applies C&D's ***own*** interpretation as to what the FDA meant by that statement; and then asks the Court to disregard ***everything else the FDA has said and done*** (and continues to say and do). Compare this to C&D's very different argument in the *Gordon* case:

> [T]he Complaint neglects to mention that C&D's supposedly "false" and "fraudulent" statements were *required* by the FDA to be included on the packaging of all latex condoms sold in the U.S. . . . Thus, in demanding that this Court enjoin C&D from selling the Product until it "cures" the alleged defects on the Product's label, ***Plaintiffs seek to substitute their judgment about the safety of N9 condoms for that of the FDA . . . .***

Gordon, 2010 WL 1220663, at 1 (N.D. Cal. Jan. 13, 2010) (emphasis added).

C&D argues that there is no question of science because the FDA has "already" spoken on the scientific issue.[8] (Opp. at 22-23.) But this point weighs in ***favor*** of the FDA's primary jurisdiction. The FDA has determined that the Weeks Estimator, which bases its results on an estimate of weeks since ovulation, is a safely marketable product with the inclusion of specific FDA-mandated disclosures that clarify that the product is different from a doctor's estimate of duration of pregnancy based on weeks since LMP. (Clearance Letter.)

C&D points out that, in the usual 510(k) process, the FDA's role is comparatively limited. Here, however, the FDA invoked Section 513(i)(1)(E), greatly expanding both its ability and its duty to control claims made by SPD on the packaging and elsewhere. 21 U.S.C. § 360c(i)(1)(E). While C&D suggests this is of no moment, the record shows that the FDA clearly took and takes its duty seriously, carefully reviewing SPD's marketing both pre- and post-clearance.

B. C&D's Argument That It Lacks A Remedy Is Incorrect And Irrelevant.

Also untenable is C&D's argument that absent court proceedings it would lack a remedy.[9] As noted above, C&D has already presented the same grievances it sets forth here to the FDA. The FDA then acted on C&D's complaint. The fact that the FDA did not require the Weeks Estimator to be pulled from the shelves is clearly a decision that C&D does not like. But this is

[8] C&D suggests that the scientific determination made by FDA is that the test cannot measure time since commencement of pregnancy. This is simply wrong. The FDA correctly accepted that the test measures weeks since ovulation (i.e., conception). The issue that the FDA determined required illumination for consumers (and therefore, hands-on review and disclosures on the Weeks Estimator packaging, insert, and various advertising pieces) was the difference between the Weeks Estimator's results estimating weeks since ovulation, and those of a doctor dating pregnancy from LMP. Even if C&D were right, however, this would still weigh strongly in favor of FDA having primary jurisdiction: the answer to the basic question of whether the Weeks Estimator can estimate time since ovulation (i.e., the start of pregnancy) at all is squarely within the FDA's scientific and medical expertise.

[9] C&D cites a single case – *Jovel*, 2013 U.S. Dist. LEXIS 139661 – to argue that its "lack of remedy" is grounds for declining to defer to the FDA. But *Jovel* stands for no such proposition. After assessing the issues in light of the four factors set forth above and declining to invoke primary jurisdiction on the ground that it was a simple false-advertising case that did not depend on violation of FDA directives, the *Jovel* Court noted in dicta that "deferral to the FDA is unlikely to result in a ***timely resolution of plaintiff's claims***." *Id*. at *22 (emphasis added). But prejudicial delay is not at issue here. C&D has already complained to the FDA, and the FDA has already responded. The FDA simply did not grant the remedy C&D was hoping for.

not "denying C&D a remedy." This is simply a case of the administrative body responding to C&D's own request, and then issuing a remedy that disappointed C&D.

III. SPD's Request For Judicial Notice Should Be Granted

C&D argues that SPD "improperly" asks this Court to take judicial notice of certain FDA correspondence because C&D did not refer to, or rely upon, these documents in its complaint. Citing *Chambers v. Time Warner, Inc.*, 282 F.3d 147, 149 (2d Cir. 2002), C&D maintains that a plaintiff's reliance on a document in its complaint is a "prerequisite" for taking judicial notice of that document when considering a motion to dismiss. (Opp. at 9.) This argument entirely misunderstands the concept of judicial notice.

A complaint's reliance on a document is but one of several recognized exceptions to the general rule that, in considering a Rule 12(b)(6) motion, the court should limit its inquiry to the factual averments made in the complaint. Reference to judicially noticeable facts and documents is a *separate* and *additional* exception to that general rule. *In re Thelen LLP*, 736 F.3d 213, 219 (2d Cir. 2013); *DiTocco v. Riordan*, 815 F. Supp. 2d 655, 665 (S.D.N.Y. 2011), *aff'd*, 496 F. App'x 126 (2d Cir. 2012); *O'Callaghan v. New York Stock Exch.*, No. 12-7247, 2013 WL 3984887 (S.D.N.Y. Aug. 2, 2013) (Nathan, J., adopting magistrate's rept. & recomm.), *aff'd*, No. 13-3370, 2014 WL 1422395 (2d Cir. Apr. 15, 2014). *Chambers* did not speak to this issue.

Having confused reliance with judicial notice, C&D failed to challenge the authorities cited in the RJN, the authenticity of the documents attached to the request, or the reliability of the facts evidenced by those documents. C&D has therefore conceded that judicial notice is proper here. *See Huerta v. Ocwen*, No. 09-5822, 2010 WL 2485936 (N.D. Cal. June 16, 2010); *Wasiak v. Cal-W. Reconveyance*, No. 11-1190, 2012 WL 1068733 (D. Nev. Mar. 29, 2012);*Van Ryzin v. CitiMortgage, Inc.*, No. 13-86, 2013 WL 1206807 (C.D. Cal. Mar. 22, 2013).

CONCLUSION

For the foregoing reasons, SPD's motion should be granted.

DATED: May 1, 2014

Respectfully submitted,

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